UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

TEVA'S TRIAL MANAGEMENT SUBMISSION

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INTRODUCTION

In thinking about the shape and scope of a trial in this case, Teva is differently situated. The direct purchaser plaintiffs themselves acknowledge this, devoting the *entirety* of their 23-page trial management "submission" (ECF No. 637) to the AstraZeneca-Ranbaxy agreement, relegating the Teva agreement to a footnote (n. 13), in which plaintiffs summarily assert that "similar questions would be posed for the Teva" agreement. Teva was also an afterthought in the proposed special jury verdict form handed up by Mr. Sobol during the December 11th conference, which states in brackets on the last page: "similar questions would be added to address separate [alleged] reverse payment agreements with Teva and DRL."

There is a good reason why plaintiffs have not yet "gotten around" to their claims against Teva – because it is readily apparent that such claims fail as matter of law. As set forth in Teva's pending motions for summary judgment (ECF No. 600, 606), the undisputed facts in the record establish that plaintiffs cannot meet their burden to prove: (i) the existence of *any* payment at all from AstraZeneca to Teva, let alone a "large, unjustified reverse payment" which satisfies *Actavis*; and (ii) that the Teva-AstraZeneca agreement caused any "delay" in Teva's generic entry, given that Teva was not the first-filer under the Hatch-Waxman statutory scheme and to this day still does not have even tentative FDA approval to sell generic Nexium. Either one of these deficiencies, standing alone, is fatal to all of plaintiffs' claims against Teva.

In the interim, Teva respectfully submits this memorandum to: (i) respond to the incomplete discussion of *Actavis* in plaintiffs' "submissions" (particularly as to Teva); (ii) object to the plaintiffs' improper characterization of the Teva-AstraZeneca settlement agreement as a "reverse payment agreement" and identify certain deficiencies in the direct purchaser plaintiffs' proposed special verdict form; and (iii) address the issue of bifurcation (as to which Teva incorporates by reference AstraZeneca's pretrial submission).

I. PLAINTIFFS IGNORE THE HOLDING IN *ACTAVIS* THAT A COMPROMISE OF A DAMAGES CLAIM FOR ALLEGEDLY LESS THAN FULL VALUE DOES NOT GIVE RISE TO A VIABLE ANTITRUST CLAIM.

In *FTC v. Actavis, Inc.* ("*Actavis*"), 133 S. Ct. 2223 (2013), the Supreme Court held that patent settlements involving reverse payments are subject to antitrust scrutiny under a rule of reason standard. But in that same ruling, the Supreme Court also held that litigants ***may*** settle patent infringement cases ***without any risk*** of antitrust liability when the settlement does not contain a "large, unjustified reverse payment" or involves "traditional settlement considerations." *Id*. at 2236-37. In so doing, the Court explicitly authorized: (i) settlements "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger," and (ii) settlements compromising a damages claim for less than the amount of the defendant's exposure, holding that such "commonplace" settlements are not "subject to antitrust liability." *Id.* at 2233, 2237.

That is Teva's situation here. It is undisputed that the settlement agreement resolving the Nexium (esomeprazole) patent litigation between AstraZeneca and Teva permits Teva to enter the market with generic Nexium by May 27, 2014 — well prior to the expiration of AstraZeneca's last Nexium patent in 2019. It is also undisputed that the Nexium settlement does not provide for a payment of any kind from AstraZeneca to Teva; plaintiffs do not even allege any payment from AstraZeneca to Teva in the Nexium settlement agreement.

Rather, plaintiffs claim that AstraZeneca made an implicit reverse payment to Teva by agreeing, at the same time it entered into the Nexium settlement, to a separate settlement agreement to resolve unrelated litigation involving AstraZeneca's patents for the drug Prilosec (omeprazole). In that case, AstraZeneca, again the branded manufacturer, sued Teva for patent infringement for Teva's at-risk launch of generic omeprazole. In the Prilosec settlement, Teva

paid $9 million ***to*** AstraZeneca to resolve all infringement claims against Teva. Plaintiffs nonetheless allege this payment ***by*** Teva was an effective payment ***to*** Teva from AstraZeneca because Teva supposedly faced potential exposure of more than $9 million. The undisputed facts, however, show there is no triable issue here.

First, settlements providing for market entry before patent expiration without any payment from the patent holder to the generic, and settlements that reflect a compromise of a patent damages claim for less than the asserted value of that claim are sanctioned under *Actavis*, and cannot form the basis for a viable antitrust claim. The *Actavis* Court expressly rejected the notion that a settlement at an amount that reflects a "discount" off the defendant's possible exposure constitutes an actionable "implicit net payment," and further held that parties do not "risk[] antitrust liability" if they enter into a settlement "allowing the generic manufacturer to enter the patentee's market, prior to expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2233, 2237. In the words of the Supreme Court:

> [W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement -- $40 million for example. See Schlidkraudt, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1046 (2004) (suggesting that this hypothetical settlement includes 'an implicit net payment' from A to B of $60 million, *i.e.*, the amount of the settlement discount)…. Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and do not intend to alter that understanding.

133 S. Ct. at 2233. The Nexium and Prilosec settlements fall squarely within this safe harbor.

Second, given that the Supreme Court recognized that settling a damages claim at a 60% "discount" is not actionable, *id.* at 2233, for such a settlement to conceivably amount to a reverse payment, it would need to involve a compromise (or "discount") completely outside the range of reasonableness — which plaintiffs here do not even allege much less present evidence to support

as to Teva. In light of the strong public policy favoring settlement, courts should not second-guess the reasonableness of business decisions to settle cases and the valuation of the same. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 200 (E.D.N.Y. 2003).

Third, even if plaintiffs were correct (and they are not) that the law permits antitrust scrutiny of the compromise of a damages claim to assess how the settlement amount compares to what the plaintiff might have stood to recover in the case, plaintiffs have no admissible evidence sufficient to prove that AstraZeneca reasonably stood to recover an amount in the Prilosec litigation that so far exceeds the $9 million settlement amount paid by Teva as to be unreasonable and thus a disguised reverse payment. Plaintiffs offer only inadmissible expert testimony on this point that should be excluded for the reasons set forth in ECF Nos. 605 and 804. Accordingly, plaintiffs cannot even prove that the Prilosec settlement reflected any kind of "discount" to Teva, let alone such a sufficient discount that it amounts to a "reverse payment."

Fourth, even if there were any triable issue as to the existence of a "reverse payment" to Teva, plaintiffs cannot prove that any such payment was "large" and "unexplained" as required by *Actavis*. 133 S. Ct. at 2236-37. Even accepting the inadmissible expert testimony proffered by plaintiffs that the Prilosec settlement supposedly reflected an effective $23 million "discount" to Teva, no reasonable jury could find this constitutes a "large" reverse payment intended to compensate Teva for "staying out" of the Nexium market until May 2014, given that plaintiffs themselves allege that Nexium sales exceed *$3 billion annually*. For this reason as well, plaintiffs' claims against Teva fail as matter of law under *Actavis*.

II. PLAINTIFFS SHOULD NOT BE PERMITTED TO CONTINUE TO CHARACTERIZE THE TEVA-ASTRAZENECA SETTLEMENT AGREEMENT AS A "REVERSE PAYMENT AGREEMENT" OR TO IGNORE KEY ELEMENTS OF THEIR CLAIMS AGAINST TEVA.

Because Teva is entitled to summary judgment for the reasons set forth in detail in ECF Nos. 601 and 607, there are no factual issues to be tried as to Teva. But assuming purely for sake of argument that the case were to proceed against Teva, the framework presented by plaintiffs to date improperly presumes that plaintiffs have already proved key elements of claims.

Most notably, plaintiffs should not be permitted under any circumstances to refer to the Teva-AstraZeneca settlement agreements as "reverse payment agreements" or "agreements to delay" as they do in their proposed jury verdict form, or as "Exclusion Payment Agreements," as they do in their respective Complaints. The words "reverse payment," "delay" and "exclusion payment" appear nowhere in the settlement agreements between Teva and AstraZeneca concerning Nexium and Prilosec. ECF No. 671-1, 671-2. While Teva maintains that there is no evidence at all of any payment to Teva (or for that matter any "delay") such that Teva is entitled to summary judgment, if the Court finds there is a triable factual issue on this score, then the existence of such payments may not be *presumed*, and it is plaintiffs' burden to prove: (i) the existence and amount of a reverse payment from AstraZeneca to Teva; (ii) that such reverse payment is "large" and "unjustified" within the meaning of *Actavis*; (iii) that such a reverse payment actually and proximately caused a delay in market entry of Teva's generic Nexium product; and (iv) that any such delay in Teva's entry actually and proximately caused all plaintiffs to suffer net overcharges.

To date, the sole special question plaintiffs have proposed relating to Teva (the second of two "Question 7's" on the last page of Mr. Sobol's proposed verdict form), improperly ignores several of the forgoing essential elements of plaintiffs' claims. Plaintiffs propose to ask the jury

only: "Is it more likely than not that Teva joined with AstraZeneca and Ranbaxy agreement [sic] to delay generic Nexium, i.e., was the AstraZeneca-Teva agreement part of an overall agreement or conspiracy with the AstraZeneca and Ranbaxy [sic] to delay generic entry?" Putting its grammatical problems aside, this question is deficient in several material respects:

First, plaintiffs' proposal fails to ask the jury to determine whether or not AstraZeneca made any "reverse payment" to Teva at all, and if yes, to determine the amount of any such payment and further, whether it was "large and unjustified." If the answer to either of those questions is negative, then there can be no possible liability as to Teva, as the Supreme Court was clear in *Actavis* that a generic company is not subject to antitrust liability if it enters into a settlement "allowing the generic manufacturer to enter the patentee's market, prior to expiration, without the patentee paying the challenger to stay out prior to that point." 133 S. Ct. at 2233, 2237. Put another way, if AstraZeneca did not pay Teva (and it did not), then whether or not the intention or effect of the Teva-AstraZeneca settlement was to delay generic entry is legally irrelevant, as there would be no evidence that Teva engaged in any illegal overt act in furtherance of the alleged conspiracy.[1]

Second, plaintiffs' proposed jury question fails to ask the jury to determine if or when Teva would have entered the market with generic Nexium absent the Teva-AstraZeneca settlement. This too is a glaring oversight, particularly given that Teva undisputedly was not the ANDA first-filer and to this day, still lacks even tentative FDA approval for its generic Nexium product. If the jury finds that, even absent the settlement, Teva would not have entered the

[1] While the proposed verdict form submitted by Mr. Sobol is largely silent as to the Teva settlement agreement, as to the AstraZeneca-Ranbaxy agreement, it improperly presumes that the existence of a reverse payment has already been proven, and simply asks the jury whether such payment was large or unjustified. This presumption is improper given that the existence of any payment is, at best for plaintiffs, a disputed factual issue. It would be highly prejudicial to ask the jury a special verdict question which could lead it to erroneously conclude that the Court has already made a factual determination regarding the existence of a reverse payment.

market with generic Nexium prior to May 27, 2014 (the licensed entry date under the settlement agreement), then once again, by definition there can be no liability as to Teva, as the settlement agreement will not have acted to "delay" Teva's entry.

Third, plaintiffs' proposed jury question ignores essential elements of an antitrust conspiracy claim – proof of an *agreement* between all of the defendants alleged to be parties to the conspiracy, and proof that each defendant committed an illegal overt act in furtherance of that conspiracy. *White v. R.M. Packer Co.*, 635 F.3d 571, 575, 577 (plaintiff claiming antitrust conspiracy must supply direct or circumstantial evidence of an agreement between the alleged co-conspirators "that is not only consistent with conspiracy, but tends to exclude the possibility of independent action"); *Apex Oil Co. v. DiMauro*, 822 F.2d 246, 252 (2d Cir. 1987) (plaintiff asserting antitrust conspiracy must prove that "defendants had a conscious commitment to a common scheme designed to achieve an unlawful objective"); *see also* ECF No. 654. Plaintiffs' proposal does not ask the jury to determine whether Teva and Ranbaxy had a conscious agreement or common scheme to act together to delay generic Nexium,as opposed to making independent business decisions whether to enter into their respective settlements with AstraZeneca. Instead, plaintiffs' proposal would impermissibly permit the jury to find a conspiracy if both the Ranbaxy and Teva agreements had the effect of delaying generic Nexium, even if there was no conscious agreement between all parties to that effect.

Accordingly, a proper verdict form as to Teva in Phase I of a bifurcated trial (per discussion below) should require the jurors to determine if plaintiffs have proved all of the following elements of their claims by a preponderance of the evidence:

- That AstraZeneca had market power in the relevant market;
- The existence of a reverse payment from AstraZeneca to Teva;
- The amount of any such reverse payment;

- That any such reverse payment to Teva was large and unjustified under the circumstances;

- That AstraZeneca's settlement with Teva was anticompetitive, *i.e.*, that the anticompetitive effects of that agreement outweighed any pro-competitive justifications;

- That but for the settlement agreements between Teva and AstraZeneca, Teva would have lawfully launched generic Nexium, with final FDA approval, and without infringing any valid Nexium patents, prior to May 27, 2014;

- The month and year that Teva would have lawfully launched generic Nexium, with final FDA approval, and without infringing any valid Nexium patents, if the AstraZeneca/Teva settlements had never happened;

- Whether Teva knowingly and willfully entered into a single conspiracy with all other defendants to delay the entry of generic Nexium through conscious commitment to a common scheme with all other defendants;

- Whether Teva engaged in an overt act in furtherance of a single conspiracy with all other Defendants;

- Whether but for Teva's participation in a single conspiracy to delay the entry of generic Nexium, one or more of the generic defendants would have lawfully launched generic Nexium, with final FDA approval, and without infringing any valid Nexium patents, prior to May 27, 2014; and

- The month and year that each generic defendant would have lawfully launched generic Nexium, with final FDA approval, and without infringing any valid Nexium patents, in the absence of the alleged single conspiracy to delay the entry of generic Nexium.

III. BIFURCATION

Regarding plaintiffs' suggested bifurcation of liability and damages, Teva joins in and incorporates by reference AstraZeneca's pretrial submission as to this issue. In brief, Teva's position is that some phasing of the trial in this matter may be appropriate, provided that: (i) Phase I includes all plaintiffs, (ii) the jury in Phase I is asked much more extensive special questions than plaintiffs have proposed in their initial draft of a verdict form;[2] and (iii) there is a "time-out" between each phase, to allow opportunity for meaningful settlement discussions, and

[2] As but one example, it is important to ask the Phase I jury to quantify the amount of any reverse payments found, so that in assessing damages, the Phase II jury will understand for what conduct it is measuring damages.

so that no single jury is required to sit for an unreasonable and unduly burdensome period of time. As for whether Phase II (injury and damages) should include all plaintiffs simultaneously (as suggested by AstraZeneca) or sequentially (first direct and then indirect purchasers), Teva believes either approach may be workable if the Court is inclined to one approach over the other.

As discussed at the status conference, a key issue in any phasing of the trial pursuant to Rule 42(b) is where and how to "draw the line" between Phase I and Phase II. Antitrust injury is an element of liability but requires a two-part inquiry: (1) whether the allegedly anti-competitive settlement agreement caused any delay in generic entry; and (2) if so, whether such delay caused each plaintiff to pay more for generic Nexium. Teva joins in AstraZeneca's proposal that it is only the second element of injury (*i.e.*, whether there were net overcharges to each plaintiff) and damages (*i.e.*, the quantum of those net overcharges) for which separate proceedings for direct and indirect purchasers in Phase II may be warranted. Teva concurs that this approach would maximize judicial economy and minimize the risk of inconsistent verdicts on all liability issues.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of January 2014, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/Laurence A. Schoen
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